PRESS RELEASE

EFSA opinion on endocrine disruptors problematic

Brussels, 21 March 2013 – The EFSA opinion report on endocrine disrupting chemicals released yesterday is problematic in a number of areas, according to the Health and Environment Alliance (HEAL) and the Chemicals Health and Environment Monitoring Trust (CHEM Trust).

The EFSA opinion is one of several inputs that contribute to the European Commission's development of criteria to identify chemicals with endocrine disrupting properties (or endocrine disruptors) (1). The Commission are formulating criteria which can be used in various EU laws, to ensure that a chemical identified as an endocrine disruptor under one law is also considered an endocrine disruptor under a different law. The mandate to develop these criteria is given in the pesticides and biocides regulations (Regulation 1107/2009 and 528/2012). These laws require the criteria in order to enable regulators to identify and ban pesticides with endocrine disrupting properties which may cause adverse effects.

Environment and Health NGOs have several criticisms of the European Food Safety Authority (EFSA) report.

"Firstly, the EFSA opinion tries to re-introduce risk assessment via the backdoor", says Gwynne Lyons of CHEM Trust. The opinion says that risk assessment makes the best use of information for the purposes of risk management (2). *"This contradicts both the spirit and letter of the EU Pesticides law, which bans endocrine disruptors for their inherently harmful nature."*

"Risk assessment is not the way forward for EDCs as it is unlikely that they have thresholds for effects, because they are acting on top of our own hormones, on a biochemical system that is already active and off the baseline. Moreover, it is well known that some EDCs can cause opposite effects at low doses as compared to high doses, such that it is impossible to be certain that so-called no observed effect levels derived by a risk assessment are really correct, without an enormous amount of animal testing – covering a very wide spectrum of doses and endpoints, which is clearly unacceptable," explained Ms Lyons.

"The EU must stick to the letter of the law, and not be deflected by those who want to pander to industry," said Lisette van Vliet, Senior Policy Adviser for HEAL.

Secondly, the EFSA report appears to be protecting "business as usual", even in the face of mounting concern about the harm caused by chemicals with endocrine disrupting properties. The EFSA report plays down much of the recent science, including the Kortenkamp State of the Art of Endocrine Disruptors report (3), which indicates that the currently available testing methods are inadequate to detect endocrine disrupting effects that are linked to many human diseases, such as breast and prostate cancer (4). The World Health Organization has also recently published a report concluding

that the internationally agreed and validated test methods “capture only a limited range of the known spectrum of endocrine disrupting effects” and that this “increases the likelihood of harmful effects in humans and wildlife being overlooked” (5).

Thirdly, the EFSA opinion is out of touch with international discussions about the existence of non monotonic dose response curves (NMDRCs) and low-dose effects (6). EFSA says that there is "a lack of international consensus in the scientific community about the existence or relevance of low-dose effects and non-monotonic dose response curves (NMDRCs)". This is one of the principle areas of discordance between EFSA and its critics who maintain such effects are well established for some endocrine disruptors. A joint conference organised by several EU member state Environment and Food agencies and the US National Institute of Environmental Health Sciences in Berlin 2012, generated a considerable measure of agreement on the existence of low dose effects amongst the participants.

Last week, the European Parliament invited the Commission to take a series of measures “to effectively protect human health and to work to reducing human short and long term exposures to endocrine disruptors where necessary (7).”

Both HEAL and CHEM Trust are calling for criteria that include all chemicals with endocrine disrupting properties, so that the criteria will protect our health and stimulate industry to search for safer alternatives.

“We urge people to support our joint call for an EDC free future”, concludes Lisette van Vliet (8).

Contact

Lisette van Vliet, Senior Policy Advisor, Health and Environment Alliance (HEAL), Email: lisette@env-health.org Tel: +32 2 234 36 45. Mob: +32 484 614 528

Gwynne Lyons, Director, Chemicals Health and Environment Monitoring Trust (CHEM Trust), Email: gwynne.lyons@chemtrust.org.uk Tel+44 1603 507 363, Mob +44 7944 422 898

Notes to editors

1. In autumn 2012, EFSA was asked by DG Health and Consumers to provide a scientific opinion on EDCs. The mandate to EFSA was called into question by several public interest organisations, in part because of concerns about EFSA’s track record on conflicts of interest and the influence of industry on EFSA. In December 2012, HEAL together with social and environmental organisations demanded a radical overhaul of European Food Safety Authority (EFSA). “We are calling for profound changes to ensure that EFSA fulfils its intended role of providing unbiased and up-to-date scientific advice to protect public health,” it said. http://www.env-health.org/resources/position-papers/article/joint-statement-calling-efsa-to

2. The opinion states “Furthermore, to inform on risk and level of concern for the purpose of risk management decisions it is the opinion of the SC that risk assessment (taking into account hazard and exposure data/predictions) makes best use of available information. EDs can therefore be treated like most other substances of concern for human health and the environment, i.e. be subject to risk assessment and not only to hazard assessment.”

3. **State of the Art of the Assessment of Endocrine Disruptors,** Authors**:** Andreas Kortenkamp et al, released February 2012. See http://www.env-health.org/resources/press-releases/article/report-paves-way-for-ban-on-gender

4. While the EFSA statement acknowledges the need for further development of testing strategies, it states that a ***reasonable complete*** suite of standardized assays is available for the oestrogen, androgen, thyroid or steroidogenesis modes in mammals and fish (our emphasis).

5. WHO/UNEP. State of the Science of Endocrine Disrupting Chemicals 2012, Summary for Decision-Makers, p. 3. It goes on to point out that for a large range of human health effects, such as female reproductive disorders and hormonal cancers, there are no viable laboratory models. This seriously hampers progress in understanding the full scale of the risks.

6. See the comprehensive review of the low dose and non-monotonic dose response (NMDR) literature (Vandenberg et al. 2012)

7. Report on the protection of public health from endocrine disrupters (2012/2066(INI)) http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+REPORT+A7-2013-0027+0+DOC+XML+V0//EN

8. See www.edc-free-europe.org

HEAL is a leading European not-for-profit organization addressing how the environment affects health in the European Union. With the support of its more than 65 member organizations, which represent health professionals, not-for-profit health insurers, patients, citizens, women, youth, and environmental experts, HEAL brings independent expertise and evidence from the health community to different decision-making processes. Members include international and Europe-wide organisations as well as national and local groups. Website: www.env-health.org

CHEM Trust (Chemicals, Health and Environment Monitoring Trust) is a UK charity which aims to protect humans and wildlife from harmful chemicals so that they play no part in causing impaired reproduction deformities, disease or deficits in neurological function. www.chemtrust.org.uk